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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,944	09/30/2003	John Hibner	END-814 - 21680.503883	7870

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/676,944	Applicant(s) HIBNER ET AL.	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 01/16/2007, new claim(s) 3-9 is/are acknowledged. The following new and reiterated grounds of rejection are set forth:

Election/Restrictions

2. Applicant's election with traverse of Species A, drawn to Figures 1-17, in the reply filed on 01/16/2007 is acknowledged. The traversal is on the ground(s) that the claims should be examined concurrently and such would result in a more efficient and thorough search. This is not found persuasive because the inventions are distinctly separate means for configuring a biopsy probed for acquiring a subcutaneous biopsy specimen.

The requirement is still deemed proper and is therefore made FINAL.

3. Claim 2 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 01/16/2007.
4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

5. The information disclosure statement(s) (IDS) submitted on 02/16/2005 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

Specification

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

7. Claim 1 is objected to because of the following informalities: the positive recitation of "and" appears to be missing after "g. means for advancing said flexible rod axially toward the distal end of said needle,". Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claims 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 7 and 8 recite the limitation "the specimen tube" in line 1. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-4 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Ritchart et al. (US 6,428,486 B2, hereinafter Ritchart).

13. For claims 1, 7 and 9, Ritchart et al discloses a handheld biopsy instrument (10) as broadly as *structurally* claimed comprising:

- a hollow, biopsy, insertion needle (20) having a tissue piecing distal tip (58) and a distally-disposed, axially-extending, open specimen port (28) disposed proximal of the tissue piecing tip (as best seen Figures 4, 5-6, 18, 20, and 22);
- an elongated, rotatable, tissue specimen cutter (22) having a distal end, wherein the distal end of the cutter is slidably received within the biopsy needle (as best seen in Figures ;

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- an elongated flexible push rod (61) slidably received within said needle and parallel to said cutter, said push rod extending to the distal end of said needle (column 7 lines 57-67);
- means for applying a first vacuum (the vacuum source positively recited in column 8 lines 53-64) within the distal end of said needle;
- means for advancing said cutter (44) toward the distal end of said needle;
- means for rotating said cutter (40) as said cutter advances within said needle;
- means for advancing said flexible push rod (column 7 lines 57-67) axially toward the distal end of said needle;
- means for rotating said flexible push rod (column 7 lines 57-67) at the distal end of said needle;
- and a removable specimen tube (26).

14. For claim 3, Ritchart et al discloses a handheld biopsy instrument (10) as broadly as *structurally* claimed, wherein the biopsy insertion needle comprises an upper lumen (23) and a lower lumen (35).

15. For claim 4, Ritchart et al discloses a handheld biopsy instrument (10) as broadly as *structurally* claimed, wherein the distal end of the cutter is received within the upper lumen (as best seen in Figures 5 and 6).

16. For claim 6, Ritchart et al discloses a handheld biopsy instrument (10) as broadly as *structurally* claimed, wherein lower lumen communicates with a source of vacuum (column 8 lines 53-64).

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17. For claim 8, Ritchart et al discloses a handheld biopsy instrument (10) as broadly as *structurally* claimed, wherein the specimen tube and the cutter are capable of advancing and retracting in unison.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Ritchart discloses the claimed invention but does not disclose expressly at least a portion of the push rod being slidably received in the lower lumen. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the biopsy device as taught by Ritchart with the portion of the push rod being slidably received in the lower lumen, because Applicant has not disclosed that the portion of the

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push rod being slidably received in the lower lumen provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with portion of the push rod being slidably received in the upper lumen as taught by Ritchart, because it provides a means for configuring a biopsy device to knock out tissue specimens in a predetermined location and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Ritchart. Therefore, it would have been an obvious matter of design choice to modify Ritchart to obtain the invention as specified in the claim(s).

Conclusion

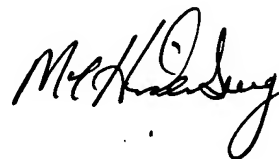
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571) 272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JH

A handwritten signature consisting of the letters 'JH' in a stylized, cursive script.A handwritten signature in cursive script, appearing to read 'M. H. [unclear]'.